

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap® Implant Systems S4 Spinal System
March 1, 2010

COMPANY: Aesculap® Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Lisa M. Boyle
610-984-9274 (phone)
610-791-6882 (fax)

TRADE NAME: S4

COMMON NAME: S4 Spinal System

REGULATION NUMBER: 888.3070 – Orthosis, Spinal Pedicle Fixation For Degenerative Disc Disease
888.3070 – Orthosis, Spinal Pedicle Fixation
888.3070 - Orthosis, Spondyloisthesis Spinal Fixation
888.3050 – Appliance, Fixation, Spinal Fixation

PRODUCT CODE: NKB, MNI, MNH, and KWP

REVIEW PANEL: Orthopedics

PURPOSE FOR PREMARKET NOTIFICATION

The S4 Spinal System described in this submission represents an expanded indication for the entire S4 system and to add components to the S4 Spinal System.

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the S4 Spinal System is substantially equivalent to the S4 Spinal System (K090657/K071945/K062085/K032219), Blackstone Pedicle Screw System (K082797), Stryker XIA 3 Spinal System (K083393), and the Depuy Expedium Spine System (K090230).

DEVICE DESCRIPTION

The S4 Spinal System consists of polyaxial screws and monoaxial screws of varying diameters and lengths, various hook styles, rods of varying lengths, and fixed and adjustable rod to rod connectors. All implant components are top loading and top tightening. The S4 Spinal System is manufactured from Titanium and Titanium alloy in accordance with ISO 5832/3 and ISO 5832/2.

INDICATIONS FOR USE

The S4 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for treatment of the following acute and chronic instabilities or deformities:

- 1) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- 2) spondylolisthesis,
- 3) trauma (i.e., fracture or dislocation),
- 4) spinal stenosis,
- 5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- 6) tumor,
- 7) pseudoarthrosis, and
- 8) failed previous fusion.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap® Implant Systems S4 Spinal System are offered in similar shapes and sizes as the predicate devices. All the components are manufactured from Titanium and Titanium Alloy, which is the same material as the predicate devices.

PERFORMANCE DATA

Static and dynamic compression bending testing in accordance with ASTM F1717 was conducted on the subject device, and the results were found to be similar to other legally marketed predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN - 9 2010

Aesculap Implant Systems, Inc.
% Ms. Lisa Boyle
Senior Regulatory Affairs Associate
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K100623

Trade Name: S4 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: April 28, 2010
Received: April 29, 2010

Dear Ms. Boyle,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", written over the printed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT510(k) Number: K100623

Device Name: Aesculap® Implant Systems S4 Spinal System


Indications for Use:

The S4 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for treatment of the following acute and chronic instabilities or deformities:

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- 7) pseudoarthrosis, and
- 8) failed previous fusion.

Prescription Use X and/or Over-the-Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

 Concurrency of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100623